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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,872	02/07/2002	John C. Alexander	3179/1Z	4170

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,872	ALEXANDER ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 25, 2006 has been entered.

Claims 45-51 are cancelled. Claims 52-60 are currently pending. The claims are now directed to the treatment of heart failure in post-acute myocardial infarction by employing a combination of three agents: eplerenone, ramipril and a loop diuretic.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 52-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO96/40257 ('257) from IDS filed September 5, 2001, Fossa (US patent 5,663,188), and Dahlstrom et al. (Am J Cardiol. 1993 Jan 21;71(3):29A-33A).

'257 teaches eplerenone as useful in treating congestive heart failure. '257 also teaches that a combination of other compounds that is a same class as eplerenone,

diuretics and ACE inhibitors captopril as useful in treating heart failure (See page 9, lines 21-24, also page 6, lines 25 – page 7, line 6).

Fossa teaches ramipril as effective in treating congestive heart failure (See col. 1, lines 50-53; claims 15, 18, and 22 for example).

Dahlstrom et al. teaches furosemide, and/or spironolactone, and/or digoxin combined with ACE inhibitor captopril as effective in treating congestive heart failure (See the abstract and page 32A-33A, discussion Section).

The references do not expressly teach the use of such combination in the method of treating congestive heart failure (CHF), especially for patients with post-acute myocardial infarction.

It would have been obvious to one of ordinary skill in the art at the time of invention to employ the combination in a method of treating post-acute myocardial infarction heart failure.

One of ordinary skill in the art would have been motivated to employ the combination of eplerenone, furosamide, and ramipril, in the herein claimed dosage, in a method of treating post-acute myocardial infarction heart failure. The herein claimed agents are known to be useful in treating congestive heart failure, both individually or in combination, therefore, concomitant employment of the herein claimed agents into a single method useful for the very same purpose, i.e., treating congestive heart failure, would be prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069). Treating post-acute myocardial infarction heart failure is merely the subset of patient population of heart failure patients. The treatment goals are essentially the same for all heart failure

patients regardless of the conditions the patients suffered before. Therefore, absent evidence to the contrary, the herein claimed combination treatment effective for treating heart failure is reasonably expected to be similarly effective in treating post-acute myocardial infarction heart failure. Furthermore, the optimization of result effect parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Response to Arguments

Applicant's arguments filed August 24, 2006 averring the cited prior arts' failure to teach the method of treating the subpopulation as herein claimed have been fully considered but they are not persuasive. As discussed above, the treatment goals of treating heart failure are essentially the same for all heart failure patients regardless of the causes of it. Therefore, if the combination are reasonably expected to be useful in treating heart failure, absent evidence to the contrary, the very same combination would also be reasonably expected to be effective in treating any subpopulation of heart failure including those are post-acute myocardial infarction.

Applicant's arguments filed August 24, 2006 averring the cited prior arts' failure to teach the herein claimed combination have been considered, but are not found persuasive. The cited prior arts clearly teaches the herein claimed agents: ramipril, and furosemide as useful individually or in combination for the treatment of heart failure. therefore, it flows logically to concomitantly employ the herein claimed agents, in the

herein claimed dosage, to treat any kind of heart failure including post-acute myocardial infarction heart failure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617